

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020859**

**CHEMISTRY REVIEW(S)**

M. 112

AUG - 9 1999

**DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS**  
**Review of Chemistry, Manufacturing, and Controls**

**NDA #:** 20-859      **CHEM. REVIEW #** 3      **REVIEW DATE:** 8/09/99

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	12/30/97	12/30/97	04/15/98 (see CR#1)
AMENDMENT [AC]	10/01/98	10/05/98	10/05/98 (see CR#1)
AMENDMENT [BC]	11/24/98	11/25/98	11/27/98 (see CR#2)
AMENDMENT [BC]	02/17/99	02/19/99	03/15/99 (see CR#2)
AMENDMENT [BC]	02/26/99	02/27/99	03/15/99 (see CR#2)
AMENDMENT [BC]	04/09/99	04/12/99	04/14/99 (see CR#2)
AMENDMENT [BC]*	07/08/99	07/09/99	07/09/99
AMENDMENT [BC]*	07/12/99	07/13/99	07/14/99
AMENDMENT [NC]*	07/10/99	07/14/99	07/14/99
AMENDMENT [NC]*	07/13/99	07/15/99	07/15/99
AMENDMENT [BC]*	07/29/99	07/30/99	08/06/99

\* Subject of this review

**NAME & ADDRESS OF APPLICANT:**

Wyeth-Ayerst Laboratories  
P.O. Box 8299  
Philadelphia, PA 19101

**DRUG PRODUCT NAME**

Proprietary:

Nonproprietary/USAN:

Code Name/#:

Chem. Type/Ther. Class:

Sonata (zaleplon) capsules

Zaleplon

Wyeth-Ayerst code designation: ZAL-846  
3S

**PHARMACOL. CATEGORY/INDICATION:**

**DOSAGE FORM:**

**STRENGTHS:**

**ROUTE OF ADMINISTRATION:**

**DISPENSED:**

Sedative hypnotic

Hard gelatin capsules

5 mg and 10 mg capsules

Oral

X Rx    OTC

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:**

See USP Dictionary of USAN and International Drug Names, 1996, page 755.

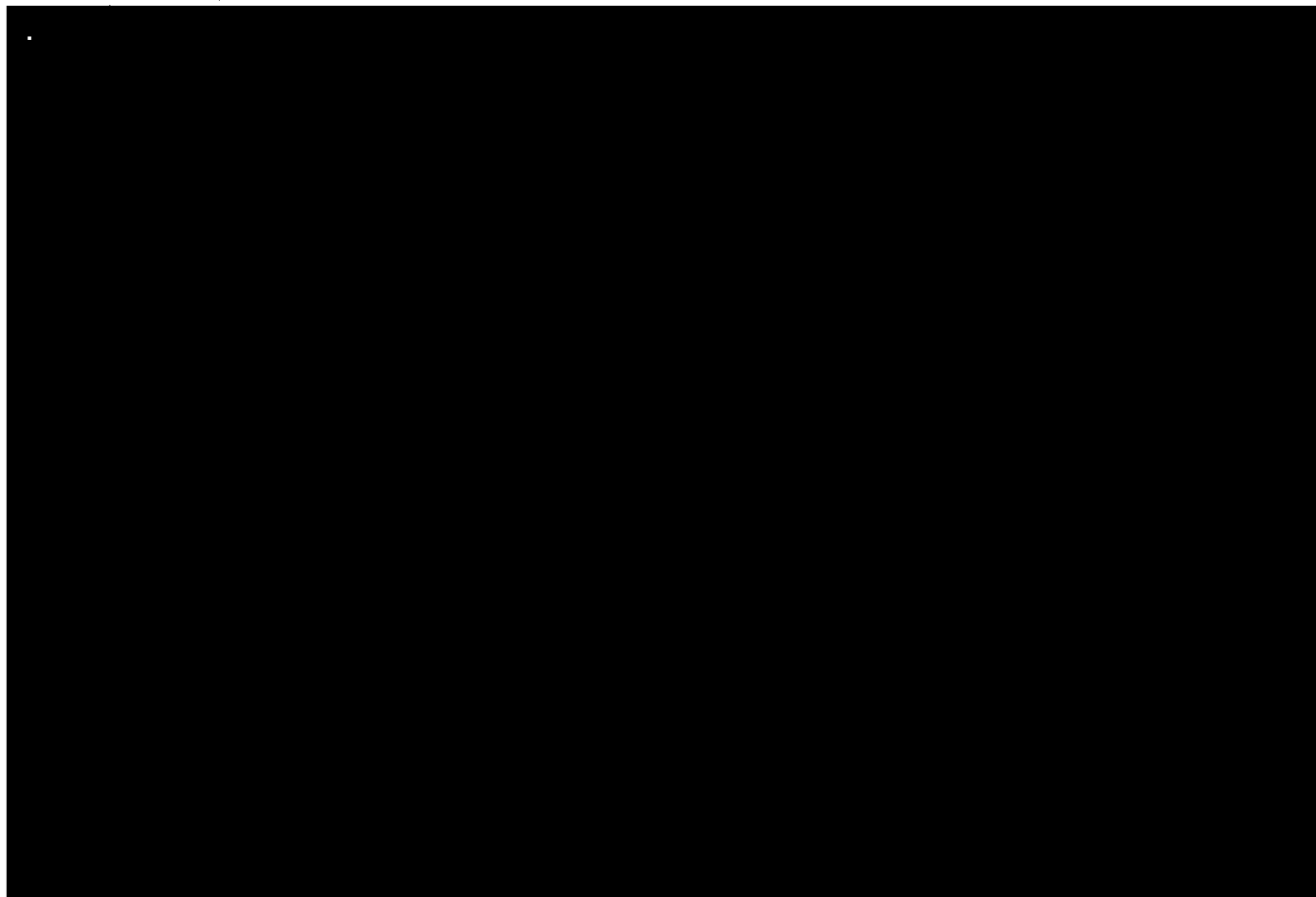
APPEARS THIS WAY ON ORIGINAL

N20859 CR#3

2

**SUPPORTING DOCUMENTS:**

**DMFs:**



**RELATED DOCUMENTS (if applicable):** IND [REDACTED]

**CONSULTS:**

EER: Acceptable. [REDACTED]

**REMARKS/COMMENTS:** The deficiencies in drug substance, drug product and container closure have been satisfactorily addressed by the applicant. The applicant's proposed 36 month shelf life for the drug product is acceptable. [REDACTED]  
[REDACTED]

APPEARS THIS WAY ON ORIGINAL

N20859 CR#3

3

**CONCLUSIONS & RECOMMENDATIONS:** From a CMC perspective, recommend APPROVAL (AP). [REDACTED]

/S/

[REDACTED] 8/09/99  
Rik Lostritto, Ph.D. Review Chemist

/S/

[REDACTED] 8/1/99  
Robert Seevers, Ph.D. Chemistry Team Leader

R/D Init by: \_\_\_\_\_

filename: C:N20859.r3

cc:

Org. NDA 20-859  
HFD-120/Division File  
HFD-120/RLostritto  
HFD-120/RSeevers  
HFD-120/MMille

**APPROVAL**

APPEARS THIS WAY ON ORIGINAL

11/12

JUN 23 1999

**DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS**  
**Review of Chemistry, Manufacturing, and Controls**

**NDA #:** 20-859      **CHEM. REVIEW #** 2      **REVIEW DATE:** 6/23/99

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	12/30/97	12/30/97	04/15/98 (see CR#1)
AMENDMENT [AC]	10/01/98	10/05/98	10/05/98 (see CR#1)
AMENDMENT [BC]*	11/24/98	11/25/98	11/27/98
AMENDMENT [BC]*	02/17/99	02/19/99	03/15/99
AMENDMENT [BC]*	02/26/99	02/27/99	03/15/99

\* Subject of this review

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Wyeth-Ayerst Laboratories  
P.O. Box 8299  
Philadelphia, PA 19101

**DRUG PRODUCT NAME**

Proprietary:

Sonata (zaleplon) capsules

Nonproprietary/USAN:

Zaleplon

Code Name/#:

Wyeth-Ayerst code designation:

ZAL-846

Chem. Type/Ther. Class:

3S

**PHARMACOL. CATEGORY/INDICATION:**

Sedative hypnotic

**DOSAGE FORM:**

Hard gelatin capsules

**STRENGTHS:**

5 mg and 10 mg capsules

**ROUTE OF ADMINISTRATION:**

Oral

**DISPENSED:**

☒ Rx ☐ OTC

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:**

See USP Dictionary of USAN and International Drug Names, 1996, page 755.

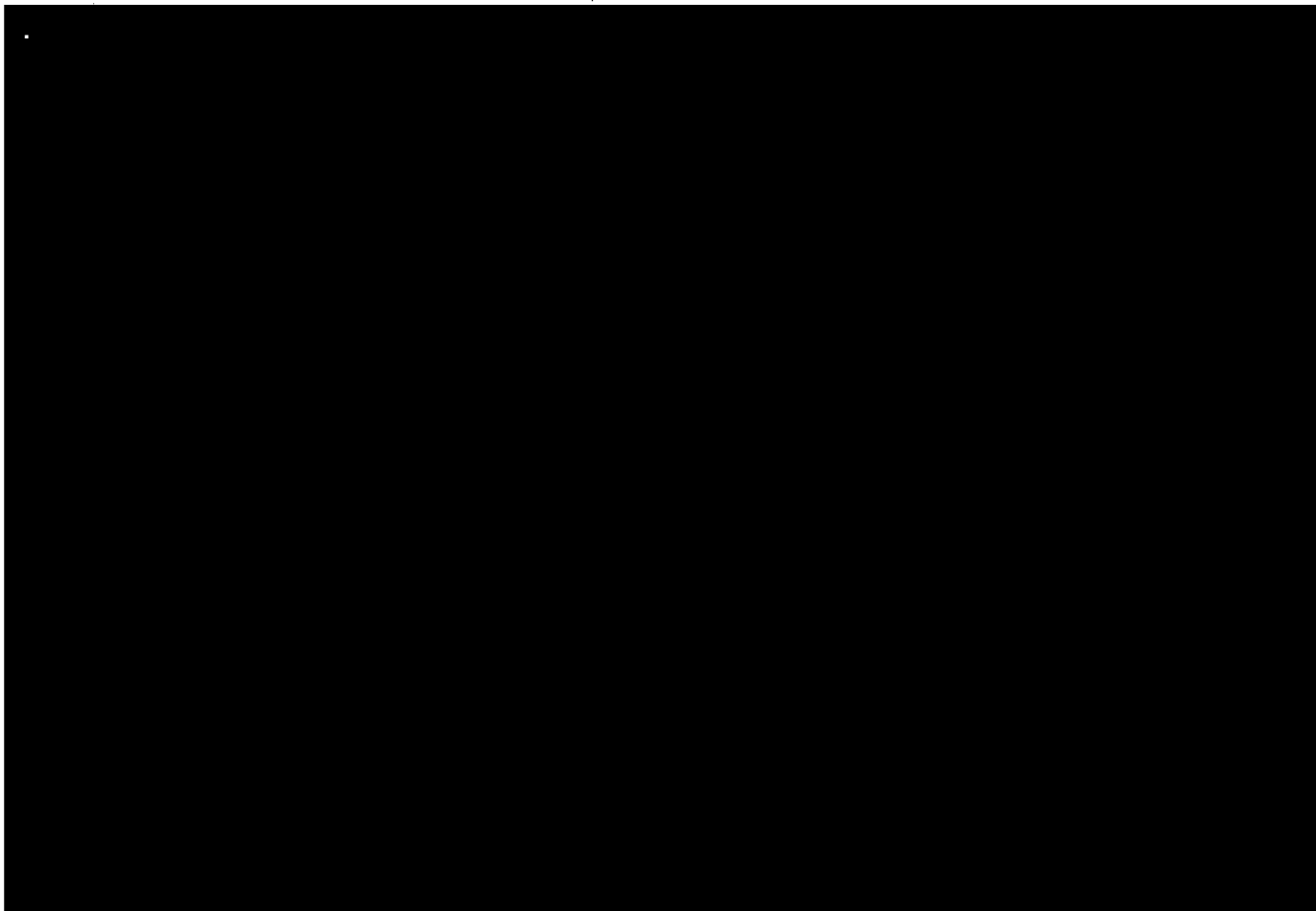
APPEARS THIS WAY ON ORIGINAL

N20859 CR#2

2

**SUPPORTING DOCUMENTS:**

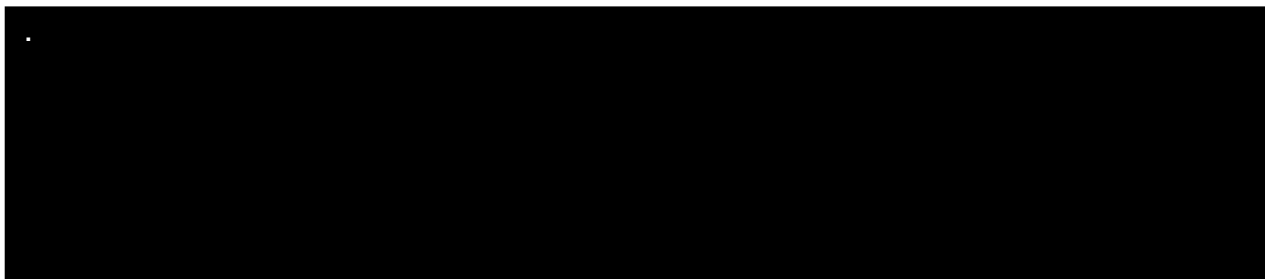
**DMFs:**



**RELATED DOCUMENTS (if applicable):** IND 

**CONSULTS:**

EER: Acceptable. Report attached in Appendix to CR#1.



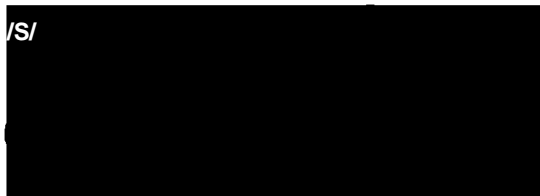
N20859 CR#2

3

**CONCLUSIONS & RECOMMENDATIONS:**

Approvable until the deficiencies noted herein are adequately responded to.

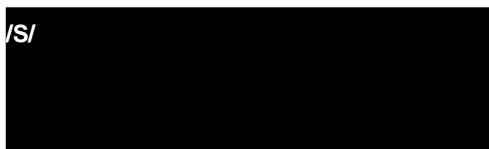
/S/



6/23/99

Rik Lostritto, Ph.D. Review Chemist

/S/



6/23/99

Robert Seevers, Ph.D. Chemistry Team Leader

R/D Init by: \_\_\_\_\_

filename: C:N20859.r2

cc:

Org. NDA 20-859

HFD-120/Division File

HFD-120/RLostritto

HFD-120/RSeevers

HFD-120/MMille

APPEARS THIS WAY ON ORIGINAL

**DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS**  
**Review of Chemistry, Manufacturing, and Controls**

**NDA #:** 20-859      **CHEM. REVIEW #** 1      **REVIEW DATE:** 10/05/98

<b>SUBMISSION TYPE</b>	<b>DOCUMENT DATE</b>	<b>CDER DATE</b>	<b>ASSIGNED DATE</b>
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ORIGINAL*	12/30/97	12/30/97	04/15/98
AMENDMENT [AC]*	10/01/98	10/05/98	10/05/98

\* Subject of this review

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Zaleplon

Wyeth-Ayerst code designation: ZAL-846  
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**DOSAGE FORM:**

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Sedative hypnotic

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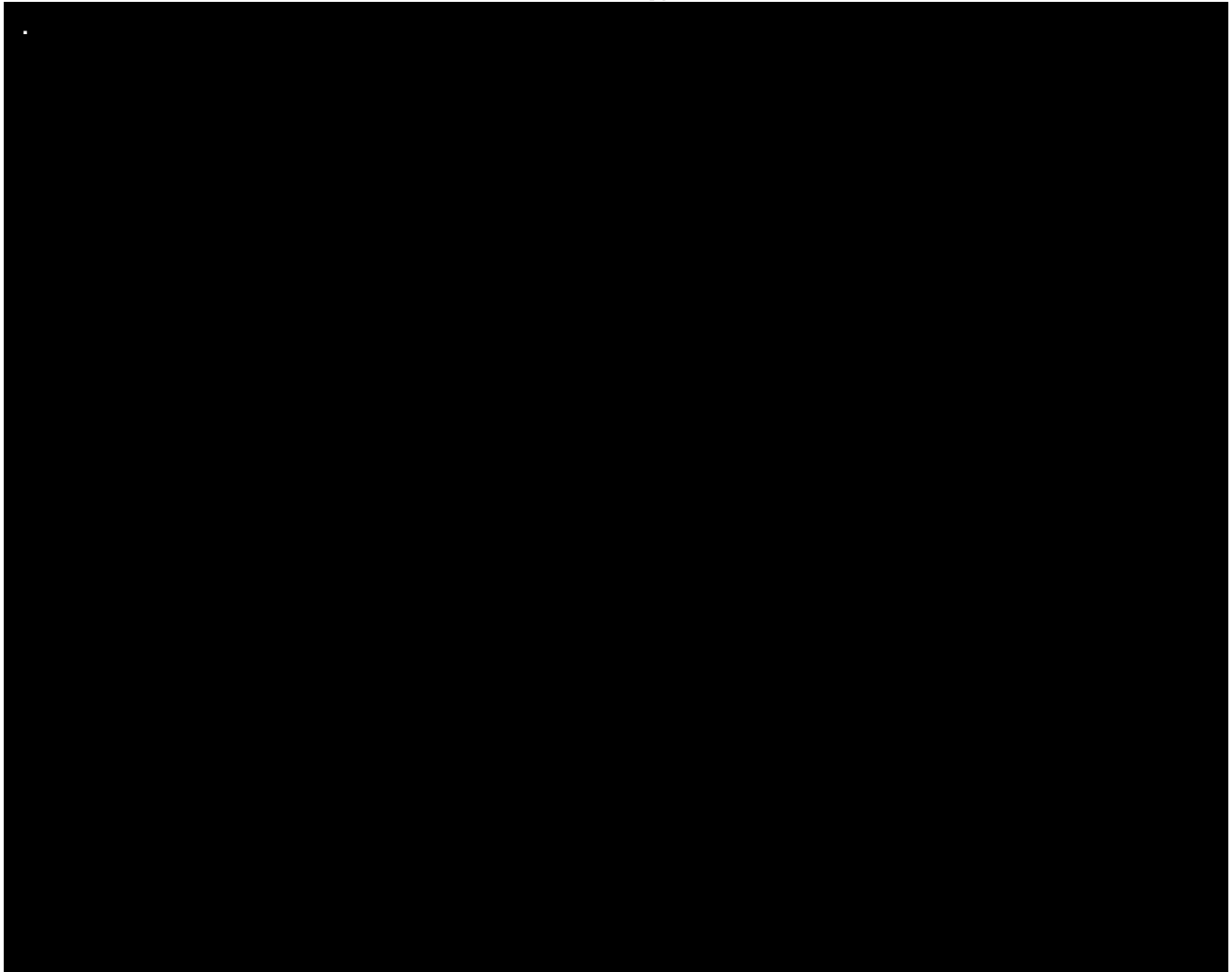
See USP Dictionary of USAN and International Drug Names, 1996, page 755.

APPEARS THIS WAY ON ORIGINAL



**SUPPORTING DOCUMENTS:**

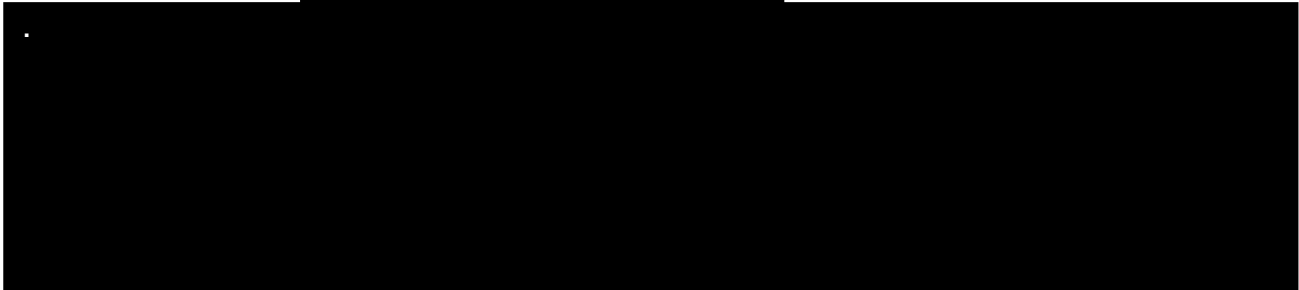
**DMFs:**



**RELATED DOCUMENTS (if applicable):** IND 

**CONSULTS:**

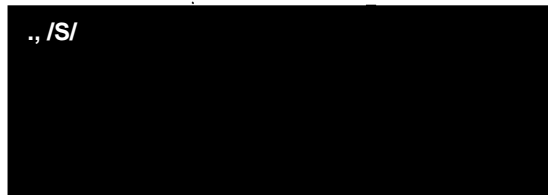
EER: Acceptable. 



**CONCLUSIONS & RECOMMENDATIONS:**

Not approvable until the deficiencies noted are adequately responded to.

./SI



10/05/98

Rik Lostritto, Ph.D. Review Chemist

/SI



10/5/98

Robert Seevers, Ph.D. Chemistry Team Leader

R/D Init by: \_\_\_\_\_

filename: C:20859r1

cc:

Org. NDA 20-859

HFD-120/Division File

HFD-120/RLostritto

HFD-120/RSeevers

HFD-120/TWheelous - APPEARS THIS WAY ON ORIGINAL

